General

Guideline Title

CDC guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management.

Bibliographic Source(s)

Schillie S, Murphy TV, Sawyer M, Ly K, Hughes E, Jiles R, de Perio MA, Reilly M, Byrd K, Ward JW, Centers for Disease Control and Prevention (CDC). CDC guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management. MMWR Recomm Rep. 2013 Dec 20;62(RR-10):1-19. [92 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Pre-Exposure Management

Education and Infrastructure

At the time of hire or matriculation, health-care providers and health-care institutions should provide training to health-care personnel (HCP) to improve recognition and encourage timely reporting of blood and body fluid exposures. The possibility that the postexposure evaluation will cause the HCP to have time lost from work should not be a barrier to reporting. Institutions should ensure that HCP have rapid access to postexposure testing and prophylaxis, including hepatitis B immune globulin (HBIG) and hepatitis B (HepB) vaccine.

Serologic Testing for HBV Infection

Testing unvaccinated HCP for hepatitis B virus (HBV) infection is not generally indicated for persons being evaluated for hepatitis B protection because of occupational risk. Prevaccination serologic testing is indicated for all persons born in geographic regions with hepatitis B surface antigen (HBsAg) prevalence of ≥2% (e.g., much of Eastern Europe, Asia, Africa, the Middle East, and the Pacific Islands) and certain indigenous populations from countries with overall low HBV endemicity (<2%); persons with behavioral exposures to HBV (e.g., men who have sex with men and past or current injection drug users); persons receiving cytotoxic or immunosuppressive therapy; and persons with liver disease of unknown etiology.

HBV endemicity (HBsAg prevalence) can be described as low (<2%), moderate (2%–<8%), and high (≥8%). Because certain persons might have been infected with HBV before they received HepB vaccination, HBsAg testing is recommended regardless of vaccination history for persons born in geographic regions with HBsAg prevalence of ≥2%, U.S.-born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity (HBsAg prevalence) (≥8%), persons who received HepB vaccination as adolescents or adults after the initiation

of risk behaviors, and persons who are human immunodeficiency virus (HIV)-positive or who receive hemodialysis.

Testing HCP at risk for HBV infection should consist of a serologic assay for HBsAg, in addition to either antibody to hepatitis B core antigen (anti-HBc) or antibody to hepatitis B surface antigen (anti-HBs). For unvaccinated HCP at risk for previous HBV infection, blood should be drawn for testing before the first dose of vaccine is administered.

Vaccination

All HCP whose work-, training-, and volunteer-related activities involve reasonably anticipated risk for exposure to blood or body fluids should be vaccinated with a complete, ≥3-dose HepB vaccine series. The Occupational Safety and Health Administration (OSHA) mandates that vaccination be available for employees within 10 days of initial assignment. HCP trainees should complete the series before the potential for exposure with blood or body fluids, when possible, as higher risk has been reported during professional training (e.g., residency training).

Incompletely vaccinated HCP should receive additional dose(s) to complete the vaccine series. The vaccine series does not need to be restarted for HCP with an incomplete series; however, minimum dosing intervals should be heeded. Minimum dosing intervals are 4 weeks between the first and second dose, 8 weeks between the second and third dose, and 16 weeks between the first and third dose.

HCP lacking documentation of HepB vaccination should be considered unvaccinated (when documentation for HepB vaccine doses is lacking) or incompletely vaccinated (when documentation for some HepB vaccine doses is lacking) and should receive additional doses to complete a documented HepB series. Health-care institutions are encouraged to seek documentation of "missing" HepB doses in the Immunization Information System (IIS), when feasible, to avoid unnecessary vaccination.

OSHA mandates that HCP who refuse HepB vaccination sign a declination statement. HCP refusing HepB vaccination can obtain vaccination at a later date at no expense if the HCP is still covered under OSHA's Bloodborne Pathogens Standard. Health-care institutions should encourage HepB vaccination among HCP to improve HBV protection and to achieve the Healthy People 2020 target of 90% vaccination.

Postvaccination Serologic Testing

HCP who have written documentation of a complete, ≥3-dose HepB vaccine series and subsequent postvaccination anti-HBs ≥10 mIU/mL are considered hepatitis B immune. Immunocompetent persons have long-term protection against HBV and do not need further periodic testing to assess anti-HBs levels.

All HCP recently vaccinated or recently completing HepB vaccination who are at risk for occupational blood or body fluid exposure should undergo anti-HBs testing. Anti-HBs testing should be performed 1 to 2 months after administration of the last dose of the vaccine series when possible. HCP with documentation of a complete ≥3-dose HepB vaccine series but no documentation of anti-HBs ≥10 mIU/mL who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation. Testing should use a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL) (e.g., enzyme-linked immunosorbent assay [ELISA]).

- Completely vaccinated HCP with anti-HBs ≥10 mIU/mL are considered hepatitis B immune. Immunocompetent persons have long-term protection and do not need further periodic testing to assess anti-HBs levels.
- Completely vaccinated HCP with anti-HBs <10 mIU/mL should receive an additional dose of HepB vaccine, followed by anti-HBs testing 1 to 2 months later. HCP whose anti-HBs remains <10 mIU/mL should receive 2 additional vaccine doses (usually 6 doses total), followed by repeat anti-HBs testing 1 to 2 months after the last dose. Alternatively, it might be more practical for very recently vaccinated HCP with anti-HBs <10 mIU/mL to receive 3 consecutive additional doses of HepB vaccine (usually 6 doses total), followed by anti-HBs testing 1 to 2 months after the last dose.

Standard Precautions and Advising HCP to Report Exposures

All HCP should adhere to infection-control guidelines and follow Standard Precautions, including the use of engineering and work-practice controls, to reduce the risk for blood or body fluid exposure. All HCP, including those who have demonstrated protection against HBV, should be advised to immediately report blood or body fluid exposures to occupational health for evaluation of the appropriate measures to prevent transmission of bloodborne pathogens (including HIV, hepatitis C, and hepatitis B).

Postexposure Management

Initial Postexposure Management

Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. Using antiseptics (e.g., 2%–4% chlorhexidine) for wound care or expressing fluid by squeezing the wound further have not

been shown to reduce the risk for HBV transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

Procedures should be followed for testing known source persons, including obtaining informed consent, in accordance with applicable laws. Source patients determined to be HBsAg-positive should be referred for appropriate management and should be reported to the state or local health department. When a source patient is unknown (e.g., as occurs from a puncture with a needle in the trash), the exposed HCP should be managed as if the source patient were HBsAg-positive. Testing needles and other sharp instruments implicated in an exposure is not recommended, regardless of whether the source patient is known or unknown. The reliability and interpretation of findings in such circumstances are unknown, and testing could be hazardous to persons handling the sharp instrument. Exposures involving human bites should be managed with the knowledge that both the person being bitten and the person who engaged in biting were potentially exposed.

Institutions should ensure that HCP have timely access to postexposure management and prophylaxis, including HBIG and HepB vaccine. For exposed HCP thought to be susceptible to HBV infection, HBIG and HepB vaccine should be administered as soon as possible after an exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG and HepB vaccine can be administered simultaneously at separate injection sites.

Anti-HBs testing of HCP who received HBIG should be performed after anti-HBs from HBIG is no longer detectable (6 months after administration). Anti-HBs testing should be performed using a method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL) (see Table 2 in the original guideline document).

Managing Vaccinated HCP

For vaccinated HCP (who have written documentation of a complete, ≥3-dose HepB vaccine series) with subsequent documented anti-HBs ≥10 mIU/mL, testing the source patient for HBsAg is unnecessary. No postexposure management for HBV is necessary, regardless of the source patient's HBsAg status.

For vaccinated HCP (who have written documentation of HepB vaccination) with anti-HBs <10 mIU/mL after two complete, ≥3-dose HepB vaccine series, the source patient should be tested for HBsAg as soon as possible after the exposure. If the source patient is HBsAg-positive or has unknown HBsAg status, the HCP should receive 2 doses of HBIG. The first dose should be administered as soon as possible after the exposure, and the second dose should be administered 1 month later. If the source patient is HBsAg-negative, neither HBIG nor HepB vaccine is necessary.

For vaccinated HCP (who have written documentation of a complete, ≥3-dose HepB vaccine series) without previous anti-HBs testing, the HCP should be tested for anti-HBs and the source patient (if known) should be tested for HBsAg as soon as possible after the exposure. Testing the source patient and the HCP should occur simultaneously; testing the source patient should not be delayed while waiting for the HCP anti-HBs test results, and likewise, testing the HCP should not be delayed while waiting for the source patient HBsAg results.

- If the HCP has anti-HBs <10 mIU/mL and the source patient is HBsAg-positive or has unknown HBsAg status, the HCP should receive 1 dose of HBIG and be revaccinated as soon as possible after the exposure. The HCP should then receive the second 2 doses to complete the second HepB vaccine series (6 doses total when accounting for the original 3-dose series) according to the vaccination schedule. To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed 1 to 2 months after the last dose of vaccine.
- If the HCP has anti-HBs <10 mIU/mL and the source patient is HBsAg-negative, the HCP should receive an additional HepB vaccine dose, followed by repeat anti-HBs testing 1 to 2 months later. HCP whose anti-HBs remains <10 mIU/mL should undergo revaccination with 2 more doses (6 doses total when accounting for the original 3-dose series). To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed 1 to 2 months after the last dose of vaccine.
- If the HCP has anti-HBs ≥10 mIU/mL at the time of the exposure, no postexposure HBV management is necessary, regardless of the source patient's HBsAg status.

Managing HCP Who Lack Documentation of Vaccination, Are Unvaccinated or Incompletely Vaccinated

For unvaccinated or incompletely vaccinated HCP (including those who refused vaccination), the source patient should be tested for HBsAg as soon as possible after the exposure. Testing unvaccinated or incompletely vaccinated HCP for anti-HBs is not necessary and is potentially misleading, because anti-HBs ≥10 mIU/mL as a correlate of vaccine-induced protection has only been determined for persons who have completed an approved vaccination series.

- If the source patient is HBsAg-positive or has unknown HBsAg status, the HCP should receive 1 dose of HBIG and 1 dose of HepB vaccine administered as soon as possible after the exposure. The HCP should complete the HepB vaccine series according to the

vaccination schedule. To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed approximately 1 to 2 months after the last dose of vaccine. Because anti-HBs testing of HCP who received HBIG should be performed after anti-HBs from HBIG is no longer detectable (6 months after administration), it will likely be necessary to defer anti-HBs testing for a period longer than 1–2 months after the last vaccine dose.
    - HCP with anti-HBs ≥10 mIU/mL after receipt of the primary vaccine series are considered immune. Immunocompetent persons have long-term protection and do not need further periodic testing to assess anti-HBs levels.
    - HCP with anti-HBs <10 mIU/mL after receipt of the primary series should be revaccinated. For these HCP, administration of a second complete 3-dose series on an appropriate schedule, followed by anti-HBs testing 1 to 2 months after the third dose, usually is more practical than conducting serologic testing after each additional dose of vaccine. To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed 1–2 months after the last dose of vaccine.
- If the source patient is HBsAg-negative, the HCP should complete the HepB vaccine series according to the vaccination schedule. To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed approximately 1 to 2 months after the last dose of vaccine.
    - HCP with anti-HBs ≥10 mIU/mL after receipt of the primary vaccine series are considered immune. Immunocompetent persons have long-term protection and do not need further periodic testing to assess anti-HBs levels.
    - HCP with anti-HBs <10 mIU/mL after receipt of the primary series should be revaccinated. For these HCP, administration of a second complete 3-dose series on an appropriate schedule, followed by anti-HBs testing 1 to 2 months after the third dose, usually is more practical than conducting serologic testing after each additional dose of vaccine. To document the HCP's vaccine response status for future exposures, anti-HBs testing should be performed 1 to 2 months after the last dose of vaccine.

Testing of HCP Exposed to an HBsAg-Positive or Unknown Source

HCP who have anti-HBs <10 mIU/mL, or who are unvaccinated or incompletely vaccinated, and who sustain a percutaneous, mucosal, or nonintact skin exposure to a source patient who is HBsAg-positive or has unknown HBsAg status should undergo baseline testing for HBV infection as soon as possible after the exposure, and follow-up testing approximately 6 months later. Testing immediately after the exposure should consist of total anti-HBc, and follow-up testing approximately 6 months later should consist of HBsAg and total anti-HBc.

HCP exposed to a source patient who is HBsAg-positive or has unknown HBsAg status do not need to take special precautions to prevent secondary transmission during the follow-up period; however, they should refrain from donating blood, plasma, organs, tissue, or semen. The exposed HCP does not need to modify sexual practices or refrain from becoming pregnant. If an exposed HCP is breast feeding, she does not need to discontinue. No modifications to an exposed HCP's patient-care responsibilities are necessary to prevent transmission to patients based solely on exposure to a source patient who is HBsAg-positive or has unknown HBsAg status.

Vaccine Nonresponders

Vaccinated HCP whose anti-HBs remains <10 mIU/mL after revaccination (i.e., after receiving a total of 6 doses) should be tested for HBsAg and anti-HBc to determine infection status. Those determined not to be HBV infected (vaccine nonresponders) should be considered susceptible to HBV infection. No specific work restrictions are recommended for vaccine nonresponders.

Documentation

Health-care institutions should maintain records, ideally electronic records that are easily retrievable following exposures, of documented vaccination histories and serologic test results for reference in managing occupational exposures, and to provide to other health-care institutions if requested by the HCP. The vaccination information should be entered into an IIS accepting records from adult vaccination, if available. HCP should be provided a copy of HepB vaccination and anti-HBs testing results and encouraged to keep them with their personal health records so they can readily be made available to future employers.

HCP with HBV Infection

HCP who are positive for HBsAg should be counseled how to prevent HBV transmission to others and referred for further evaluation. Those who perform exposure-prone procedures should be advised regarding the procedures they can perform safely as per updated Centers for Disease Control and Prevention (CDC) recommendations for the management of HBsAg-positive health-care providers and students. Chronic hepatitis B infection in itself should not preclude the practice or study of medicine, surgery, dentistry, or allied health professions.

Clinical Algorithm(s)

An algorithm titled "Pre-exposure Evaluation for Health-care Personnel Previously Vaccinated with Complete, ≥3-dose HepB Vaccine Series

Who Have Not Had Postvaccination Serologic Testing" is provided in the original guideline document.

Scope

Disease/Condition(s)

Hepatitis B virus (HBV) infection

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Dentistry

Family Practice

Geriatrics

Infectious Diseases

Internal Medicine

Nursing

Pathology

Pediatrics

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Clinical Laboratory Personnel

Dentists

Emergency Medical Technicians/Paramedics

Health Care Providers

Hospitals

Nurses

Occupational Therapists

Other

Pharmacists

Physical Therapists

Physician Assistants

Physicians

Public Health Departments

Students

Guideline Objective(s)

- To examine approaches for assessing hepatitis B virus (HBV) protection for vaccinated health-care personnel (HCP)
- To provide guidance for persons working, training, or volunteering in health-care settings who have documented hepatitis B (HepB) vaccination received years before hire or matriculation (e.g., when HepB vaccination was received as part of routine infant [recommended since 1991] or catch-up adolescent [recommended since 1995] vaccination)
- To offer additional guidance for postexposure evaluation and testing of HCP

Target Population

Persons working, training, or volunteering in health-care settings who have documented hepatitis B (HepB) vaccination received years before hire or matriculation (e.g., when HepB vaccination was received as part of routine infant [recommended since 1991] or catch-up adolescent [recommended since 1995] vaccination)

Note: This guidance applies but is not limited to health-care personnel (HCP) in acute-care hospitals, long-term–care facilities (e.g., nursing homes, skilled nursing facilities, and assisted living facilities), physician's offices, dental offices, rehabilitation centers, urgent-care centers, ambulatory surgical centers, dialysis centers, and outpatient clinics, and to persons who provide home health care and emergency medical services. Although this guidance pertains to HCP, the same principles might be applicable to persons in other professions with reasonably anticipated risk for blood or body fluid exposure (e.g., public safety workers, embalmers, and crime scene cleanup crews).

Interventions and Practices Considered

1. Pre-exposure management
    - Providing training to health-care personnel (HCP) to improve recognition and encourage timely reporting of blood and body fluid exposures
    - Ensuring that HCP have rapid access to postexposure testing and prophylaxis, including hepatitis B immune globulin (HBIG) and hepatitis B (HepB) vaccine
2. Serologic testing for hepatitis B virus (HBV) infection
    - Prevaccination serologic testing in indicated populations
    - Serologic assay for hepatitis B surface antigen (HBsAg), in addition to either antibody to hepatitis B core antigen (anti-HBc) or antibody to hepatitis B surface antigen (anti-HBs)
3. Vaccination with a complete, ≥3-dose HepB vaccine series
4. Standard precautions and advising HCP to report exposures
5. Postexposure management
    - Washing wounds and skin sites that have been in contact with blood or body fluids with soap and water
    - Flushing mucous membranes with water
    - Testing known source persons, including obtaining informed consent, in accordance with applicable laws
    - Referral of source patients determined to be HBsAg-positive for appropriate management and reporting to the state or local health department
    - Ensuring that HCP have timely access to postexposure management and prophylaxis, including HBIG and HepB vaccine
    - Managing vaccinated HCP
    - Managing HCP who lack documentation of vaccination, are unvaccinated or incompletely vaccinated
    - Testing of HCP exposed to an HBsAg-positive or unknown source

6. Management of vaccine nonresponders
7. Documentation of all vaccination histories and serologic test results
8. Management of HCP with HBV infection
    - Counseling in how to prevent HBV transmission to others and referral for further evaluation
    - Advice regarding health-care procedures that can be performed safely

Major Outcomes Considered

- Rate of hepatitis B virus (HBV) infections in the United States
- Risk for occupational blood or body fluid exposures
- Health-care personnel (HCP) reporting of blood or body fluid exposures
- Hepatitis B vaccination coverage among HCP
- Proportion of adults with measurable antibodies to hepatitis B surface antigen (anti-HBs) at intervals after vaccination
- Duration of vaccine-induced protection
- Vaccination and postvaccination serologic testing practices
- Cost-effectiveness of approaches for assessing HBV protection among HCP

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

The expert panel reviewed relevant published literature identified through PubMed searches, citations, and personal files. Reference lists were reviewed to retrieve additional relevant information. The expert panel considered the changing epidemiology of hepatitis B virus (HBV) infections from surveillance reports, which included follow-up with state health departments to obtain additional information on health-care personnel (HCP) with acute HBV during 2005–2010 reported as having a positive or unknown hepatitis B (HepB) vaccination history. The expert panel reviewed previous recommendations from Advisory Committee on Immunization Practices (ACIP), Healthcare Infection Control Practices Advisory Committee (HICPAC), and the U.S. Public Health Service, including recommendations defining HCP at risk for occupational exposure, HepB vaccination, and postvaccination serologic testing. The panel also reviewed postexposure prophylaxis, and results from an electronic survey administered to health-care institutions regarding current practices. Various members of the expert panel were consulted to address issues throughout the development of these guidelines.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Decision Analysis

Review

Description of the Methods Used to Analyze the Evidence

Evidence was summarized in presentations discussed during expert panel teleconferences.

To examine the cost-effectiveness of various strategies for assessing health-care personnel (HCP) protection from hepatitis B virus (HBV), two economic models that yielded calculations of the incremental cost per quality-adjusted life-year (QALY) saved were developed. See the "Cost Analysis" field.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In 2012, the Centers for Disease Control and Prevention (CDC) identified and convened subject matter experts in the fields of hepatitis B virus (HBV) infection, health-care epidemiology, and evidence-based medicine to form an expert panel to address mechanisms for assessing HBV protection for vaccinated health-care personnel (HCP). The expert panel was comprised of professionals from academic medicine (e.g., pediatrics, family medicine, internal medicine, and infectious diseases) and occupational health; federal and state public health professionals with expertise in hepatitis and health-care associated infections; and liaisons from the Society for Healthcare Epidemiology of America (SHEA), Healthcare Infection Control Practices Advisory Committee (HICPAC), American Medical Directors Association (AMDA), American College Health Association (ACHA), American Academy of Family Physicians (AAFP), and the Society for Adolescent Health and Medicine (SAHM). The expert panel convened 21 teleconferences for deliberations during January 19, 2012–January 8, 2013. Materials for teleconference discussion were electronically distributed to members.

The panel identified two approaches for assessing HBV protection for vaccinated HCP, on the basis of expert opinion, which form the foundation of this guidance. Members of the expert panel critically reviewed earlier drafts of this guidance document, which was developed by CDC, individually and as a group by teleconference.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Cost-Effectiveness Considerations

To examine the cost-effectiveness of various strategies for assessing health-care personnel (HCP) protection from hepatitis B virus (HBV), two economic models that yielded calculations of the incremental cost per quality-adjusted life-year (QALY) saved were developed. One model represented an approach in which antibody to hepatitis B surface antigen (anti-HBs) is measured on a pre-exposure basis, and HCP with anti-HBs <10 mIU/mL receive an additional dose of hepatitis B (HepB) vaccine, followed by repeat anti-HBs measurement. If anti-HBs remains <10 mIU/mL after the first revaccination dose, the HCP receives two additional revaccination doses of HepB vaccine followed by repeat anti-HBs measurement. Another model represented a postexposure management approach; at the time of exposure, the HCP is tested for anti-HBs and the source patient is tested simultaneously for hepatitis B surface antigen (HBsAg), and postexposure prophylaxis would be administered on the basis of these results. Results from the two models were compared. A decision-tree analysis was used to combine all parameters and calculate the total

intervention costs and probability of infection. In addition, HBV infection-related costs and QALY loss (accounting for acute and asymptomatic infections and a 6% probability of chronic infection) were determined from an existing model and were considered for the HCP's remaining lifetime. The intervention time frame included a 1-year analysis and a multiyear analysis covering up to 10 years of exposure. A 3% annual discount rate was used, and all final cost figures were converted to 2010 U.S. dollars using the Medical Consumer Price Index.

The baseline cost-effectiveness models assumed that an ideal 95% of HCP have initial and sustained protection against HBV infection after a primary ≥3-dose HepB vaccine series, irrespective of the presence of detectable anti-HBs. Ninety-five percent protection was derived from the proportion of persons aged <40 years, including term newborns that have measurable anti-HBs ≥10 mIU/mL soon after a primary vaccination series. Approximately 18 to 25 years after vaccination, approximately 20% of HCP (vaccinated at age <1 year) or approximately 80% of HCP (vaccinated at age ≥1 year) retain anti-HBs ≥10 mIU/mL. The model did not account for unrecognized exposures, as probability data for unrecognized exposures are not available, or suboptimal vaccine coverage that exists among HCP.

For pre-exposure anti-HBs testing followed by revaccination and retesting, if necessary, compared with doing nothing, the incremental cost per QALY saved was $4,542,467 for trainees and $3,149,183 for nontrainees at year one, and decreased to $893,619 and $796,140, respectively, over 10 years. This approach is expected to result in 3.7 and 1.6 visits to occupational health for trainees and nontrainees, respectively. The expected number of infections is 0.7 per 100,000 and 0.4 per 100,000 for trainees and nontrainees, respectively. For an approach relying upon postexposure management, compared with doing nothing, the incremental cost per QALY saved was $2,270,801 for trainees and $1,610,998 for nontrainees at year one, and decreased to $917,859 and $1,114,364 respectively, over 10 years. The expected number of infections is 3.0 per 100,000 and 1.7 per 100,000 for trainees and nontrainees, respectively. Although an approach relying upon postexposure management might be less costly per QALY saved initially for many institutions, pre-exposure anti-HBs testing with possible revaccination becomes more cost-effective compared with a postexposure approach over time.

Sensitivity analyses demonstrated that cost-effectiveness improves in settings where a greater proportion of source patients are HBsAg-positive and among HCP with higher risk for exposure (e.g., surgeons). Cost-effectiveness can change as new antivirals become available for treatment of HBV infection. Vaccinating previously unvaccinated HCP trainees followed by postvaccination serologic testing, compared with doing nothing, has an incremental cost per QALY saved of $374,646 at year one and $51,537 over 10 years, accounting for direct costs to the health-care system and direct medical costs of hepatitis B-related illness and complications.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

Members of the expert panel critically reviewed earlier drafts of this guidance document, which was developed by the Centers for Disease Control and Prevention (CDC), individually and as a group by teleconference.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

This report can guide clinicians, occupational health and student health clinicians, infection-control specialists, hospital and health-care training program administrators, and others in selection of an approach for assessing hepatitis B virus (HBV) protection for vaccinated health-care personnel (HCP).

Potential Harms

- The most frequently reported side effects of hepatitis B (HepB) vaccine are pain at the injection site (3%–29%) and temperature of >99.9°F (1%–6%).
- Epidemiologic and mechanistic assessment by the Institute of Medicine for 27 adverse events supported a causal association with HepB vaccination only for anaphylaxis in persons who are sensitive to yeast.
- Serious adverse effects from hepatitis B immune globulin (HBIG), when administered as recommended, are rare. Local pain and tenderness at the injection site, urticaria, and angioedema might occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin (IG) preparations.

Contraindications

Contraindications

- Hepatitis B (HepB) vaccination is contraindicated for persons with a history of hypersensitivity to yeast or any vaccine component.
- Persons with a history of serious adverse events (e.g., anaphylaxis) after receipt of HepB vaccine should not receive additional doses.
- As with other vaccines, vaccination of persons with moderate or severe acute illness, with or without fever, should be deferred until illness resolves.

Qualifying Statements

Qualifying Statements

- Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.
- References to non-Centers for Disease Control and Prevention (CDC) sites on the Internet are provided as a service to *MMWR* readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. CDC is not responsible for the content of these sites. URL addresses listed in *MMWR* were current as of the date of publication.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Schillie S, Murphy TV, Sawyer M, Ly K, Hughes E, Jiles R, de Perio MA, Reilly M, Byrd K, Ward JW, Centers for Disease Control and Prevention (CDC). CDC guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management. MMWR Recomm Rep. 2013 Dec 20;62(RR-10):1-19. [92 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

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Guideline Developer(s)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

Source(s) of Funding

United States Government

Guideline Committee

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Financial Disclosures/Conflicts of Interest

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The developers of these guidelines wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products or suppliers of commercial services related to vaccines including any related to hepatitis B vaccines, with the following exceptions: David Weber, MD, wishes to disclose that he served as a consultant and on a speakers' bureau, whether paid or unpaid (e.g., travel related reimbursement, honoraria), for the following vaccine manufacturers: Merck, Sanofi, and Pfizer pharmaceutical companies. Amy B. Middleman, MD, also wishes to disclose that she received grant funding from the following pharmaceutical companies: MedImmune, Sanofi, and Merck.

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Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site .

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238

Availability of Companion Documents

A continuing education examination is available from the Centers from Disease Control and Prevention (CDC) Web site .

Information on postexposure prophylaxis and hepatitis and specific settings is available from the CDC Web site .

Patient Resources

None available

NGC Status

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